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Development and Experimental Application of Contact Probe Catheter for Laser Angioplasty

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A sapphire contact probe laser catheter was developed to increase the dimensions of tunnels created by laser angioplasty. The device consisted of a round sapphire probe (2.2 mm diameter) attached to an 8F catheter into which a 0.2 mm optical fiber was inserted with a tip maintained at 3 mm from the sapphire. The fiber was connected to a continuous wave neodymium yttrium aluminum garnet (Nd-YAG) laser. A saline perfusate was circulated through the catheter during laser emissions to prevent excessive heating of the fiber tip.

The system was used in vitro on 16 sections of atherosclerotic calcified human cadaver aortic walls, using diluted blood as a medium, at powers ranging from 10 to 40 W and exposure times from 1 to 4 seconds. Six craters were created at each energy level. The system was also used on six human cadaver, agar-embedded, obstructed iliac and femoral arteries, using 40 W and 2 second laser emissions. Dimensions of probe-created craters were compared with those obtained using bare fibers. The shape of the probe craters was that of a truncated cone with the entry hole wider than the exit, as opposed to the cylindrical shape created with unmodified bare fibers. At 120 J (seconds × watts), areas of entry and exit probe-formed holes were greater than those created with the bare fibers (6.7 ± 0.5 and 3.4 ± 0.6 versus 0.2 ± 0.01 mm^2, respectively, $p < 0.001$). The tissue ablation velocity of the probe was 20 times that of the bare fiber (0.5 ± 0.1 versus 10.3 ± 1.0 mm^3, at 40 W for 2 seconds, $p < 0.001$).

There was a thin rim of carbonization at the edges of the craters similar to that created with bare fibers. Tissue adherence on the sapphire was reduced with 1 second exposure times. No alterations in the structure of the fiber tip were found using the probe catheter as opposed to bare fibers. This laser delivery system is superior to bare fibers and is able to create large holes without either excessive thermal injury to the arterial wall or damage to the optical fiber tip.

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The first clinical attempts (1–4) to recanalize obstructed arteries using laser angioplasty have demonstrated feasible but incomplete arterial recanalization requiring complementary balloon angioplasty to further widen the laser-created tunnels. Thus, the need for a laser device that is effective and able to create large holes without increasing the risk of arterial perforation is apparent. Both experimental and clinical studies (5,6) have shown that high power can be used to reduce the duration of exposure, thus minimizing heat transfer to adjacent arterial walls. High power laser ablation, however, is associated with back burning of the optical fiber at the distal end (7). A modified or new laser device must also protect the fiber against damage. Accordingly, a new laser probe system was developed and its effects were examined using obstructed arteries in an in vitro model of human cadaver atherosclerotic aortic wall. The effects of the laser probe system on the integrity of the optical fiber distal tip were also analyzed.

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Methods

Laser catheter (Fig. 1). A contact laser probe made of a selected physiologically neutral synthetic sapphire crystal with great mechanical strength, low thermal conductivity and a high melting temperature (2,050°C) was used (Surgical Laser Technologies). The laser probe was screwed onto a metal universal connector attached to an 8F woven Dacron catheter (United States Catheter and Instrument Co.,

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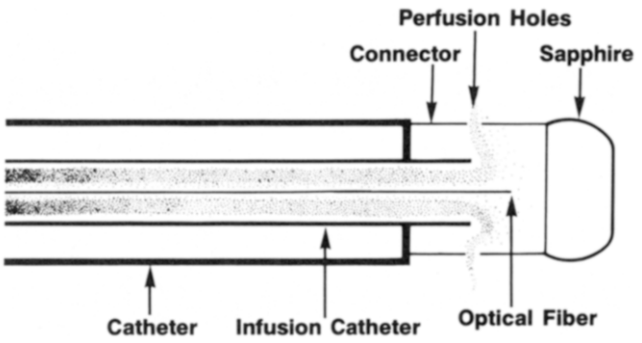

Figure 1. Laser angioplasty catheter with the sapphire connected to the catheter. During laser emissions, a saline perfusate was circulated to prevent burning of the optical fiber tip.

Inc.). To increase the flexibility of the laser catheter relative to the 0.6 mm optical fiber that is conventionally used with contact probes, a 0.2 mm optical fiber (Advanced Cardiovascular Systems) was inserted into the catheter and maintained at 3 mm beyond the end of the connector. The optical fiber was connected to a neodymium yttrium aluminum garnet (Nd-YAG) laser (Messerschmitt-Bölkow-Blohm). Saline perfusate was circulated (10 ml/min) through the catheter to prevent excessive heating of the fiber tip. The contact probe had a round shape that resulted in high power density and broad energy delivery. The outside diameter of the connector and the probe was 2.2 mm. These contact probes have been used previously for gastrointestinal applications. The laser power required to achieve a given power density at the tissue surface was 12 times less with contact than with noncontact Nd-YAG probes (8,9).

In vitro model: arterial walls. The system was used on 16 atherosclerotic human cadaver aortic walls immersed in a 20% diluted blood bath. Each sample was submitted to six laser emissions perpendicular to the tissue with the laser sapphire probe fixed against the target at varying powers and exposure times ranging from 10 to 40 W and 1 to 4 seconds, respectively. The energy increments were arbitrarily chosen. Power above 40 W could not be used because of burning of the fiber. For technical reasons, the equipment could not be used at emission times of less than 1 second.

Measurements. The diameter of holes created at the entry and exit of craters and the depth of penetration were measured using an ocular micrometer mounted on a dissecting microscope. Because the shape of tunnels created with bare fibers and the sapphire probe approximated cylinders and truncated cones, respectively, the volume of tissue destroyed was calculated using the formulas: $\pi r^2 h$ and $\pi h/3 (r^2_1 + r_1 r_2 + r^2_2)$, respectively, where r = radius of the hole in millimeters and h = depth of hole in millimeters.

Embedded arteries. In addition, an in vitro model consisting of six normal and atherosclerotic human cadaver arteries embedded in agar was used. The arteries were positioned into plastic boxes, embedded and connected to plastic tubes. During the embedding procedure, cold saline solution was infused through the artery using a closed circuit pump to prevent agar fluid from penetrating the artery. In normal and partially obstructed arteries, a target (piece of arterial wall) was sutured perpendicularly to the long axis of the artery in order to create an occlusion. The target consisted of a circular piece of tissue cut from an atherosclerotic, calcified human cadaver aortic wall. This target occlusion could only be penetrated by a laser beam and could not be crossed by an angioplasty guide wire. The created laser hole could not be further widened by a balloon catheter.

The laser catheter was inserted into the artery through an introducer and the tip was placed against the target. The experiments were performed under direct observation through transparent agar using a helium neon red aiming beam, with two-dimensional ultrasound imaging and angiography. During the procedure, a diluted blood (20%) perfusate was circulated through the closed circuit at a flow rate of 30 ml/min. Laser emissions of 40 W and 2 seconds each were used with the probe in contact with the target. After each emission, the laser catheter was advanced to keep close contact between the sapphire probe and the target. Recanalization was considered successful when a hole was created and the catheter passed through the target. After the procedure, both the artery and the target were submitted to gross and histologic examination.

Laser calibration. The actual power of laser emission was measured with a power meter at the entry of the fiber, at the laser fiber coupling interface, at the distal end of the fiber and with the distal tip covered by the sapphire probe. Calibration was made using the helium neon beam and the Nd-YAG beam at 10 W as it exited from the laser. After the laser emissions, the fiber was examined and the power available at the fiber tip was measured.

Histologic examination. Human arteries obtained from cadavers at autopsy were routinely placed in normal saline solution. After gross examination, specimens were fixed in 10% neutral buffered formalin and representative tissue blocks were obtained for microscopic evaluation. These represented cross sections of arterial walls in their full thickness and were embedded in paraffin. Sections were cut with a rotary microtome at 5 mm intervals and stained with hematoxylin-eosin. Selected sections were stained with the Masson trichrome method for collagen and with the Verhoeff-van Gieson technique for elastic and collagen fibers. Gross examination was particularly directed to the assessment of the diameter and depth of the tunnels produced by laser, the status of the adjacent arterial wall and evaluation

of the degree of atherosclerosis. In addition to these variables, the extent of tissue carbonization and thermal damage at laser emission sites were evaluated microscopically.

Statistical analysis. One-way analysis of variance was used to evaluate the results in different energy level groups. An unpaired Student's *t* test was used to analyze the differences between the bare fiber and probe catheter variables. A probability level of less than 0.05 was considered significant.

Results

Power calibrations. Calibration of the laser device showed that the power at the bare fiber distal tip was reduced to nearly 55% of that at the proximal end, whereas the output at the contact probe was reduced to 20% of that at the proximal end; that is, there was an output energy at the bare fiber tip and the sapphire probe of 22 and 8 W, respectively.

Tissue ablation (Fig. 2 and 3). At the same level of input energy (40 W × 3 seconds), the volume of tissue removed with the probe was 200% greater (10.3 ± 1.0 versus 0.5 ± 0.1 mm^3) than that removed with the bare fiber. Increasing levels of energy resulted in significantly greater ablated volume ($p \leq 0.01$). With the bare fiber, the tunnel obtained had a cylindrical shape and an identical area at the entry and the exit. By contrast, with the probe the tunnel obtained had the shape of a truncated cone (Fig. 3). The area at the probe entry was greater than that at the exit for any given delivered energy (Table 1). The area of holes at either the entry or the exit was greater than that created with the bare fiber even at lower energy levels (5.11 ± 0.25 and 1.07 ± 0.16, respectively, versus 0.22 ± 0.07 mm^2). At similar energy levels (120 J, 40 W × 3 seconds), the probe areas were 10 to 30 times greater than the bare fiber areas (6.74 ± 0.54 and 3.43 ± 0.60 versus 0.22 ± 0.07 mm^2, respectively). By contrast, the depth of penetration was not different between the bare fiber and the probe (2.0 ± 0.3 versus 2.1 ± 0.3 mm).

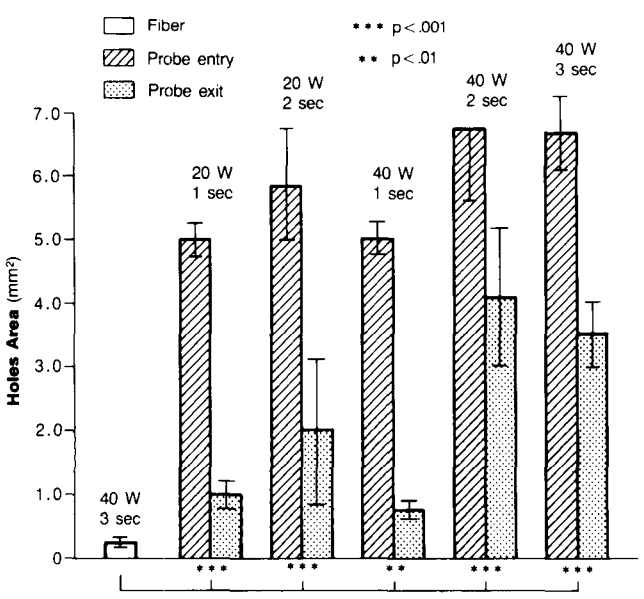

Figure 2. Area of holes created with the bare fiber and the contact probe at the entry and exit.

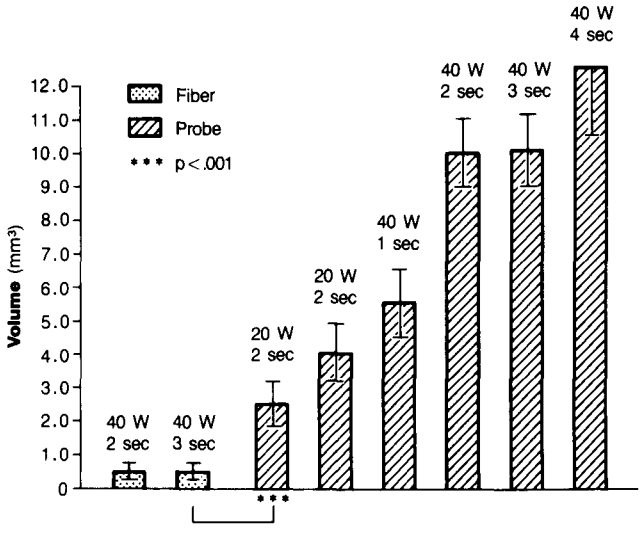

Figure 3. Volume of atherosclerotic tissue destroyed with the bare fiber and the contact probe.

Target crater results: (Fig. 4). To penetrate the targets within the embedded arteries, the probe had to be maintained in close contact with the target. Dimensions of the tunnels were similar to those obtained in aortic walls. Two to three laser emissions of 40 W at the laser exit and a duration of emission of 2 seconds each were required to totally penetrate the targets. The depth of the tunnel through the targets was 2.5 ± 0.4 mm.

Histologic results (Fig. 5). Laser emission by contact probe resulted in sharply demarcated tunnels in the aortic wall, which were ovoid to round with average measurements at the intimal surface of 3.2 × 2.5 mm (maximal diameter) at the intimal surface. These holes were characteristically conical with the largest diameter at the point of entrance. Gradually the diameter narrowed as the laser hole penetrated the aortic wall. A narrow rim of carbonized tissue, 10 to 20 μm wide, lined the laser hole. Peripherally there was a variable width zone of vacuolization and local disruption of the aortic tissue. This zone of vacuolization was 300 to 400 μm wide and represented thermal damage. Vacuolization caused by thermal effect was more pronounced and more extensive in the aortic medial layer than in the sclerotic intima. Laser emission with the bare fiber resulted in holes with a maximal diameter of 1.2 × 1.0 mm. Their shape was cylindrical rather than conical, so that they exhibited a uniform diameter. The carbonization rim was slightly wider

Table 1. Volume of Tissue Destroyed and Area of Craters at Entry and Exit

	Fiber	Contact Probe							
	120 J	20 J	40 J		80 J	120 J		160 J	
	40 W × 3 seconds (n = 6)	20 W × 1 second (n = 6)	20 W × 2 seconds (n = 6)	40 W × 1 second (n = 6)	40 W × 2 seconds (n = 6)	40 W × 3 seconds (n = 6)		40 W × 4 seconds (n = 6)	
Volume (mm^3)	0.49 ± 0.14	2.67 ± 0.11*	3.97 ± 0.80*	5.63 ± 0.92*	9.96 ± 1.53*	10.32 ± 1.01*		12.45 ± 1.95*	
Area entry (mm^2)	0.22 ± 0.07	5.11 ± 0.24*	5.84 ± 0.96*	5.04 ± 0.25*	6.81 ± 1.22*	6.74 ± 0.54*		8.99 ± 2.03*	
Area exit (mm^2)	0.22 ± 0.07	1.07 ± 0.16†	2.04 ± 1.42†	0.71 ± 0.56†	4.16 ± 1.41	3.43 ± 0.60†		2.94 ± 0.58†	
Depth (mm)	2.0 ± 0.3	0.9 ± 0.2	1.1 ± 0.3	2.0 ± 0.3	2.1 ± 0.3	2.1 ± 0.3		2.2 ± 0.4	

*$p < 0.001$ versus fiber; †$p < 0.001$ versus entry.

than that produced with the contact probe (10 to 30 μm wide). Vacuolization caused by thermal effect was slightly more extensive and more pronounced as compared with that resulting from the contact probe (300 to 500 μm wide). There was no evidence of laser carbonization or vacuolization in serially sectioned vascular walls in the embedded arteries. Aside from the previously described alterations, arterial wall damage specifically related to laser emission and underlying atherosclerosis has not been observed in tissue more than 0.5 mm away from the laser emission.

Catheter guidance/visualization. Laser catheter guidance was facilitated by the rounded, smooth distal tip, which showed no tendency toward entrapment into the arterial wall. Control of catheter placement was facilitated by ultrasonography indicating correct positioning of the catheter tip against the plaque even though optimal image visualization was slightly hindered by the echogenic metal adaptor located behind the sapphire tip. Each laser irradiation was associated with an emission of bubbles, arising from the site of the target, which corresponded to the conversion of the solid phase matter to soluble gas.

The slightly curved agar-embedded arteries mimicked human leg arteries surrounded by muscle and soft tissue. The laser catheter was easily guided through both straight and curved segments of the arteries.

Tissue adherence. Adherence of tissue to the sapphire was observed with exposure times of 2 or more seconds. A reduction in the amount of tissue adhering to the sapphire was clearly observed when exposure times were shortened to 1 second. Tissue adherence could also be prevented by leaving the power on during disengagement of the tip. Despite the numerous emissions, the tip did not exhibit major alterations in shape or color. Adherent particles were easily removed with peroxide solution.

Fiber tip alterations. After laser emissions, no structural alterations of the fiber tip were found when saline solution was used as a perfusate; however, blood perfusion resulted in burning of the distal end. The significant reduction in power that occurs with the bare fiber did not occur with the contact probe. With the contact probe, neither the catheter nor the connector was altered after laser emissions.

Discussion

Early works (10–14) convincingly demonstrated that laser irradiation could vaporize atherosclerotic plaque in vitro. Laser elimination of atherosclerotic plaque through optical fibers able to transmit laser energy has been established (15).

Limitations of conventional laser catheters. Besides vessel wall perforation (16,17), the main limitation of currently available laser angioplasty catheters is the small size of the holes and tunnels they are able to create. Argon and Nd-YAG continuous wave emissions as well as pulsed excimer lasers (18–20) have been used, but holes at the entry

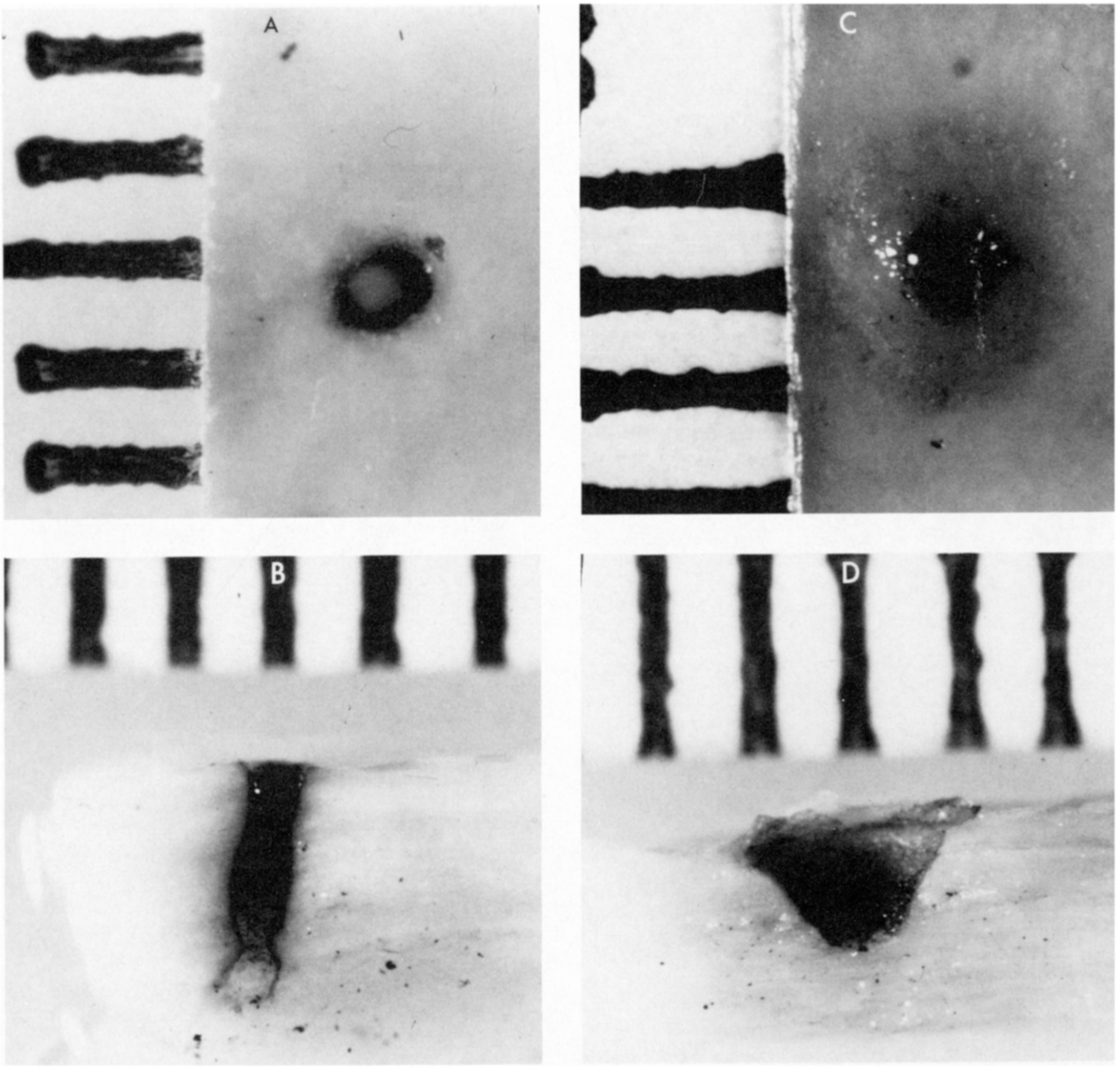

Figure 4. Frontal and cross-sectional views of holes created using the bare fiber (**A,B**) and the contact probe (**C,D**).

to the obstruction were hardly greater than 1 to 1.5 mm in diameter and were even smaller (0.4 mm) with pulsed laser delivery. Therefore, it was proposed that the laser beam be used for preliminary hole boring, with subsequent extensive recanalization eventually completed by balloon angioplasty. This process has been performed in patients using either a continuous wave laser delivery system with argon (1,2), Nd-YAG (3) or hot tip thermal angioplasty (21). The major drawback of this combined approach is that the immediate evaluation of the intrinsic effects of laser cannot be achieved, and manipulating catheters across laser-recanalized arteries exposed to laser irradiation, and thus potentially fragile, could be harmful to the arterial wall.

Size of laser-created holes. Thus, larger laser-created holes are required to eliminate atherosclerotic plaques from arteries in order to totally recanalize obstructed vessels. Our device created holes as wide as 3 to 3.5 mm in diameter with a resultant truncated cone shape having a relatively

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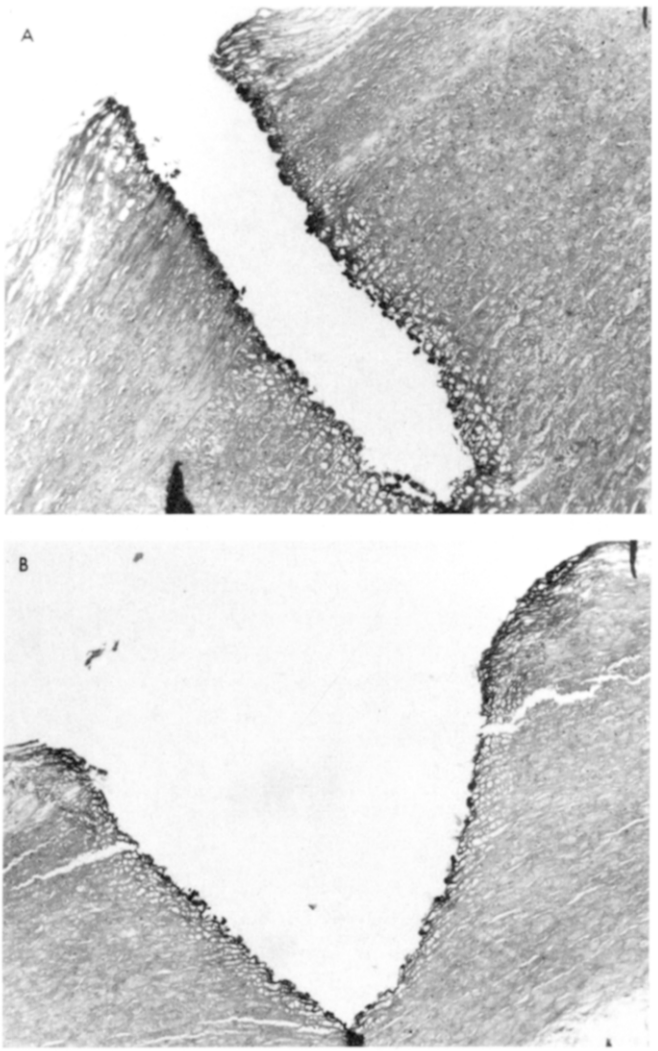

Figure 5. **A**, Laser cut with bare fiber. The shape is cylindrical and the carbonized rim is wider than that resulting from laser irradiation with the sapphire contact probe. Hematoxylin-eosin, original magnification × 16, reduced by 43%. **B**, Laser cut with sapphire contact probe. Note the conical shape, the narrow rim of carbonized tissue and the zone of vacuolization peripheral to the carbonized tissue, which is more prominent at the medial layer. Hematoxylin-eosin, original magnification × 12.5, reduced by 43%.

large entry diameter. This crater pattern allowed a balloon angioplasty catheter to be advanced easily through the previously occluded segment. Holes created with bare fibers were too small to allow insertion of a catheter into the tunnel. The efficiency of the system was high as compared with that observed with the bare fiber tip. The ablation velocity of tissue removed in terms of volume of vaporized atherosclerotic tissue within 2 seconds was 10.32 ± 1.01 versus 0.49 ± 0.14 mm^2 at 40 W. Thus, for a given input energy, 20 times more tissue could be destroyed with the probe than with the bare fiber, despite a loss of energy incurred through the contact probe. The loss could be due at least in part to back reflection of the laser beam from the sapphire probe. The comparatively higher efficiency of the contact probe is thought to be due to two factors: 1) contact laser probes create a well defined localized region of high power density at the tip of the probe, which is placed precisely against the target tissue, and 2) energy loss to backscatter is minimized as compared with 40% of the beam energy that can be lost with bare fibers. Because of improved efficiency, the duration of the laser angioplasty procedure is anticipated to be shorter with the contact probe. Moreover, because the tunnels created are larger, it is also anticipated that no complementary balloon angioplasty procedure would be required.

Protection of laser fiber and arterial wall. Another advantage of this system is that the laser fiber is protected from burning, which frequently occurred during powerful laser emissions in blood. With this device, the fiber did not melt and laser emissions were delivered without a loss of power at the tip.

The arterial wall was also protected from mechanical injury that may occur at the cutting edge of the standard quartz fiber tip. The histologic comparison between bare fiber-created holes and those made with the sapphire probe demonstrated a reduction in the degree of carbonization relative to the size of holes created with our catheter. Gross and microscopic examination did not identify thermal injury to the arterial wall, demonstrating that the vessel wall was protected from indirect heating. Absence of arterial wall perforation was confirmed by observations with echography and no extravasation of contrast medium on angiography. Adherence of tissue was observed at high energy levels, that is, at high powers and long exposure times. This could be obviated by decreasing the energy level, that is, reducing exposure time. This observation is in agreement with those of Daikuzono and Joffe (8) and Joffe (9) on experimental liver resections.

The other concerns about the technique include risk of distal embolization and follow-up of the laser-irradiated site. It has been suggested that downstream release of debris is unlikely to result in major distal embolization (22,23). The healing process occurs after laser emission within 2 to 8 weeks, and recurrence of atherosclerotic stenosis is unlikely (24).

Increased flexibility of laser catheter. The contact laser delivery system that is currently used in surgery employs a thick, stiff optical fiber 0.6 mm in diameter (8,9). This catheter obviously could not be inserted into arteries for percutaneous or intraoperative laser angioplasty. Coupling a 0.2 mm optical fiber with the probe allowed the flexible catheter to be utilized and inserted into arteries as small as 4 mm in diameter. If the size of the sapphire probe can be reduced, it is anticipated that the flexibility of the optical fiber would allow contact probes adapted to small catheters to be inserted into coronary arteries. An alternative would

be to mount the contact probe directly on to the optical fiber, further reducing the size of the laser catheter.

In this study, the sapphire probe was used only with an Nd-YAG laser source. However, because of the optical properties of the synthetic sapphire, it is speculated that other wavelengths could be used. Nevertheless, Nd-YAG seems to be the most appropriate source because it is easy to transmit through flexible fiber optics, is diffusely absorbed by all protein molecules and is extremely reliable. Although short emission times resulted in high efficiency and lack of tissue adhesion, further studies are required to determine the feasibility and effectiveness of pulsed delivery systems associated with sapphire probes.

Implications. These preliminary data are encouraging. This new design was able to create larger holes than those obtained with bare fibers at a reduced risk of perforating the vessel wall. Although the laser probe appeared to be easy to guide, its use remains limited to straight, medium sized arteries because of the width of the catheter tip. With continued research, almost complete recanalization is anticipated in obstructed arteries nearly 5 mm in diameter, and with miniaturized probes, smaller arteries, such as coronary arteries, would be amenable to laser recanalization.

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